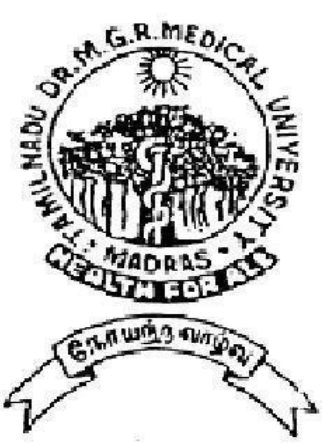
COMPARATIVE STUDY ON HEALING OF DIABETIC PLANTAR FOOT ULCERS TREATED BY CONVENTIONAL MEASURES ALONE VS CONVENTIONAL MEASURES ALONG WITH BOHLER IRON PLASTER CAST

A DISSERTATION SUBMITTED TO THE TAMILNADU
DR.M.G.R MEDICAL UNIVERSITY
CHENNAI

In partial fulfilment of the Regulations
for the award of Degree of

M.S.(GENERAL SURGERY)BRANCH -I



DEPARMENT OF GENERAL SURGERY
MADURAI MEDICAL COLLEGE
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Date:
Place: Madurai

Dr.P.AMUTHA M.S.,
Professor & Unit Chief,
Department of General Surgery,
Madurai Medical College,
Madurai.

CERTIFICATE BY THE HEAD OF DEPARTMENT

This is to certify that the dissertation entitled "**COMPARATIVE STUDY ON HEALING OF DIABETIC PLANTAR FOOT ULCERS TREATED BY CONVENTIONAL MEASURES ALONE VS CONVENTIONAL MEASURES ALONG WITH BOHLER IRON PLASTER CAST"** is a bonafide research work done by **Dr.D.PREMKUMAR,** M.S. Post graduate student in the Department of General Surgery, Madurai Medical College & Hospital, Madurai, under the guidance of **DR.P.AMUTHA M.S.,**Professor, Department of General Surgery, Madurai Medical College, GRH, Madurai in partial fulfillment of the requirements for the degree of M.S. in General Surgery.

Date:
Place: Madurai

Dr.S.R.DHAMODHARAN M.S.,
Professor & Head of the Department,
Department of General Surgery,
Madurai Medical College,
Madurai.

CETIFICATE BY THE HEAD OF THE INSTITUTION

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Date:

Place: Madurai **Prof.Dr.D.MARUTHUPANDIAN M.S.,**

DEAN

Madurai Medical College,

Madurai.

DECLARATION BY THE CANDIDATE

I ,**Dr.D.PREMKUMAR** solemnly declare that the dissertation titled **"COMPARATIVE STUDY ON HEALING OF DIABETIC PLANTAR FOOT ULCERS TREATED BY CONVENTIONAL MEASURES ALONE VS CONVENTIONAL MEASURES ALONG WITH BOHLER IRON PLASTER CAST "** is a bonfide and genuine research work carried out by me under the guidance of DR.P.AMUTHA,M.S., Professor, Department of General Surgery, Madurai Medical College, Madurai.

The Tamilnadu Dr.M.G.R Medical University, Chennai shall have the rights to preserve,use and disseminate this dissertation in print or electronic format for academic/research purpose.

Place: Madurai
Date:

Dr. D.PREMKUMAR,
Postgraduate in General Surgery,
Department of General Surgery,
Madurai Medical College,
Madurai.

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I whole heartedly thank all the patients who willingly co-operated and rendered themselves for the study without whom this study couldn't have been a reality.

Place: Madurai
Date:

Dr. D.PREMKUMAR
Postgraduate in General Surgery,
Department of General Surgery,
Madurai Medical College,
Madurai.

TABLE OF CONTENTS

INTRODUCTION

India , being diabetic capital of the world and the most common complication of diabetes mellitus is diabetic foot ulcer.

The major tenets in diabetic foot ulcer healing are

1. Debridement
2. Regular dressings
3. Appropriate antibiotics if infection supervenes
4. Offloading (pressure dispersion from ulcer site)

Offloading of unperceived areas of plantar stress is critical for preventing and effectively treating diabetic foot ulcer disease.

The complications of diabetes mellitus can be acute or chronic based on presentation. Acute complications includes diabetic ketoacidosis, Hyperglycemic hyperosmolar state and hypoglycemia. Chronic microvascular complications includes retinopathy,nephropathy,neuropathy and diabetic foot ulcer disease. Macrovascular complications includes accelerated atherosclerosis,myocardial infarction, stroke and lower extremity gangrene.

COMPLICATIONS OF DIABETIC ULCER FOOT

1.Spreading cellulitis

2.multiple deeper abscess

3.septicemia

4.diabetic ketoacidosis

Finally leads to unexpected consequences like amputation which results in major morbidity and mortality in most diabetic ulcer disease patients.Hence appropriate management of diabetic foot ulcers with conventional dressings along with offloading device hastens ulcer healing thus preventing complications.

AIMS AND OBJECTIVES

The aim of the study is to compare the healing of diabetic plantar foot ulcers when treated with conventional measures alone vs conventional measures along with bohler iron plaster cast.Thus by using bohler iron plaster cast it enables visualization of ulcer through the window made in the cast which favours daily dressing and minimal debridement.

Bohler iron plaster cast provides complete offloading of foot thus causing dispersion of pressure points away from ulcer site .

REVIEW OF LITERATURE

HISTORY OF DIABETES

Diabetes had been affecting lives for thousands of years. An ailment suspected to be diabetes was identified by Egyptians in early 1550 B.C Ancient Indians were aware of this condition for which they tested and called honey urine , by observing ants are attracted to a person's urine.

In greek diabetes means "to go through". It was named by greek physician Apollonius Memphis keeping in consideration the top symptom of excessive passing of urine through our body.

In 1926,Edward Albert Sharpey-Schafer identified pancreas of the diabetic patients were not able to produce a chemical substance named insulin which break downs sugar. Thus excessive sugar comes out through urine.

ANATOMY OF HUMAN FOOT

It bears weight and allows locomotion and it has,

- 26 bones,
- 33 joints(20 actively articulated),
- More than 100 muscles,tendons and ligaments.
- It is divided into hindfoot, midfoot and forefoot.

HIND FOOT

It is composed of

- Talus,
- Calcaneum.

Tibia and fibula are connected to the top of talus by subtalar joint.

Calcaneum is the largest bone of foot.

MIDFOOT

It is composed of

- Cuboid,
- Navicular,
- Three cuneiform bones.

It forms the arches of foot.

It acts as a shock absorber.

It is connected to hindfoot and fore foot by muscles and plantar fascia.

FOREFOOT

It is composed of

- Five toes,
- Corresponding five metatarsals ,phalanges.

It includes metatarsophalangeal and interphalangeal joints.

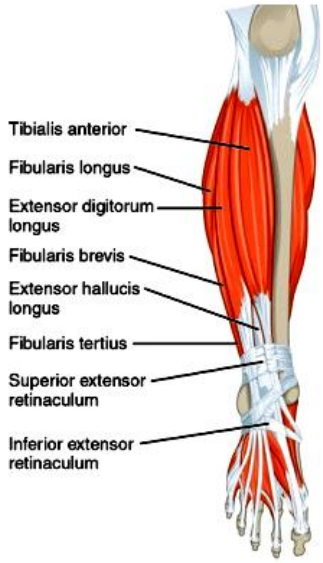
It act as a main propellant during locomotion.

MUSCLES OF FOOT

- Extrinsic muscles
- Intrinsic muscles

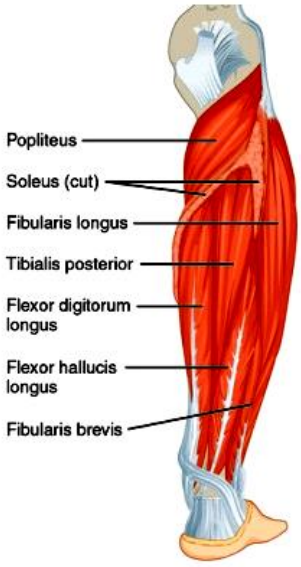
EXTRINSIC MUSCLES OF FOOT

- It originates from lower leg and attached to foot bones.
- It includes anterior group, peroneal group and posterior group.



Superficial muscles of the right lower leg (anterior view)

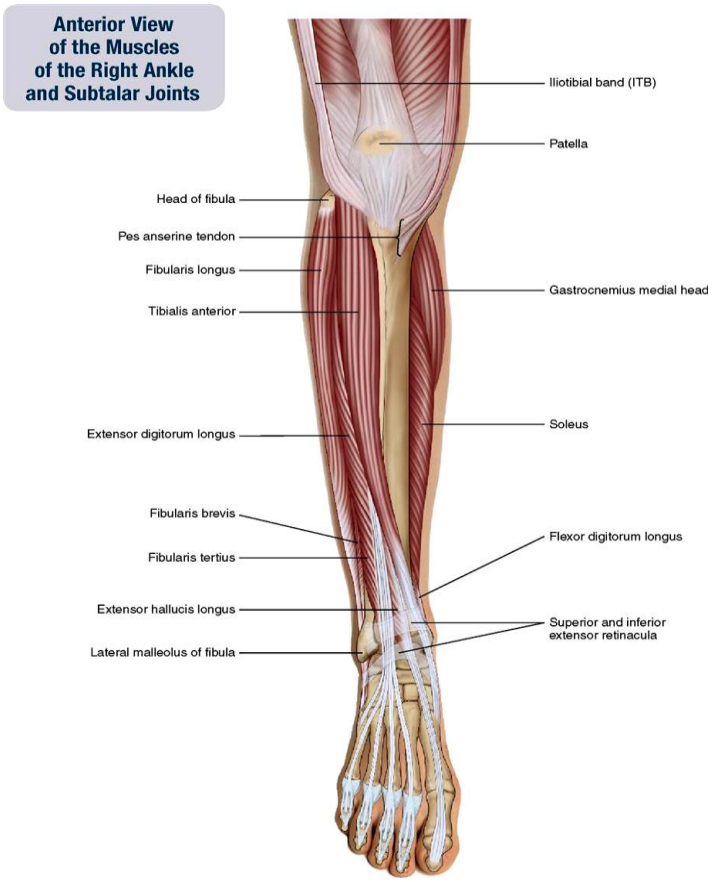
Superficial muscles of the right lower leg (posterior view)



Deep muscles of the right lower leg (posterior view)

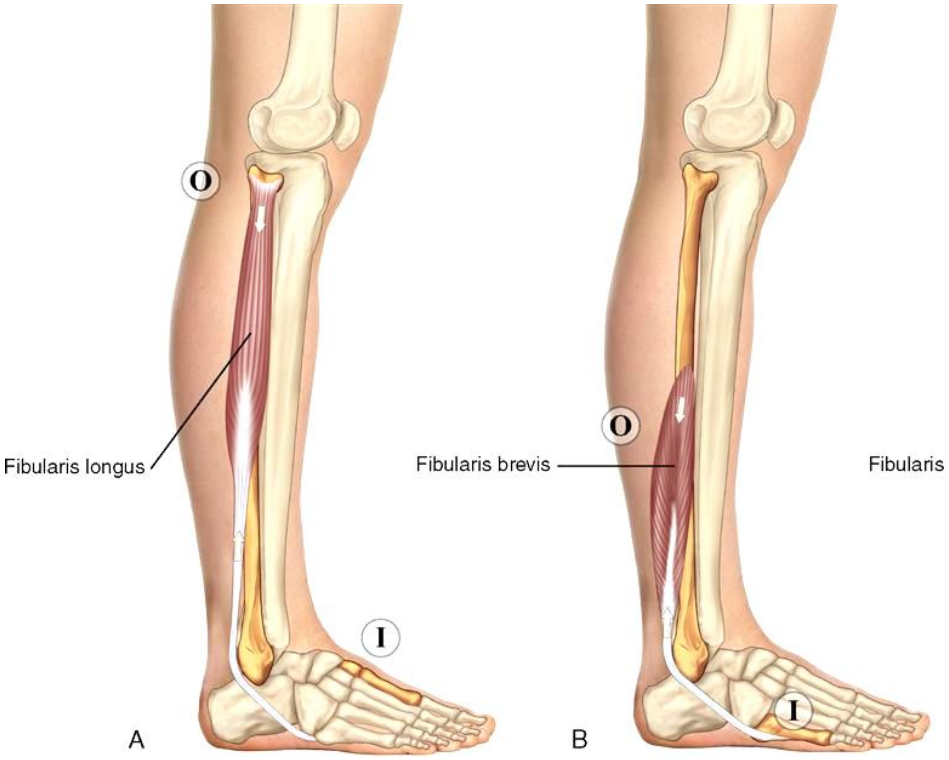
Anterior group of muscles formed by,

- Tibialis anterior,
- Extensor digitorum longus,
- Extensor hallucis longus.



Peroneal group of muscles includes

- Peroneus longus,
- Peroneus brevis.

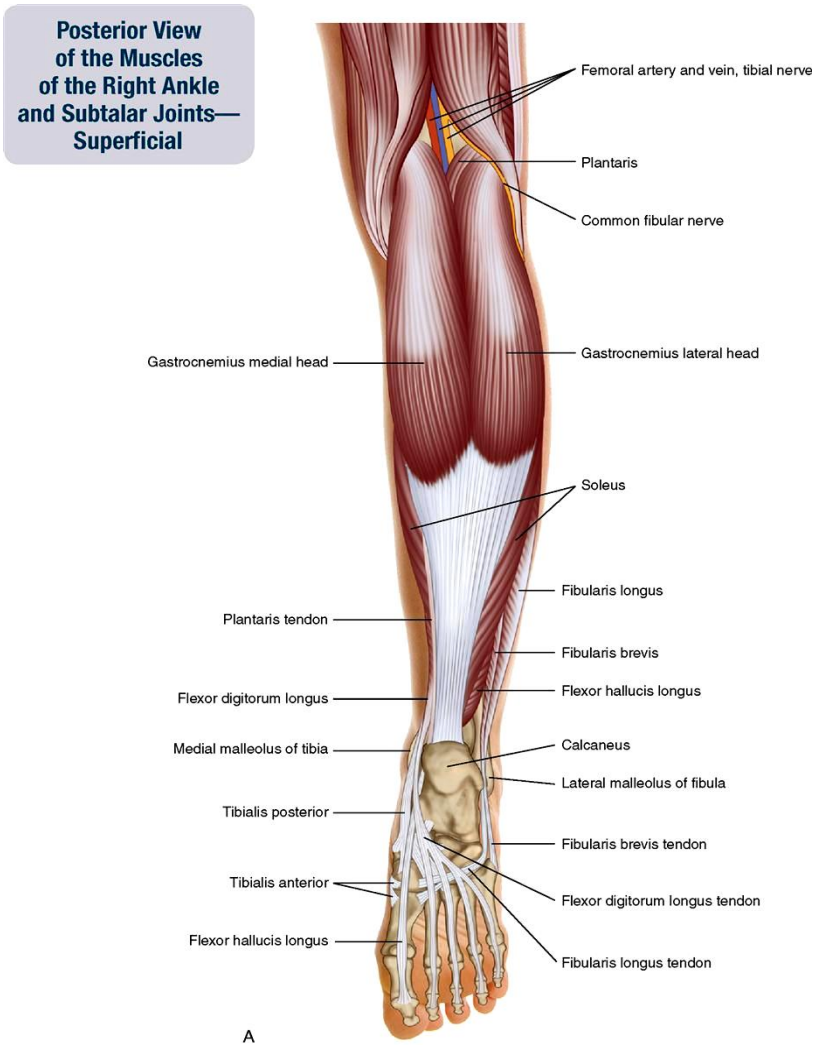


Posterior group of muscles formed by superficial layer and deep layer.

Superficial layer formed by,

- Soleus,
- Gastrocnemius,
- Plantaris.

All merge to form Achilles tendon



Deep layer formed by

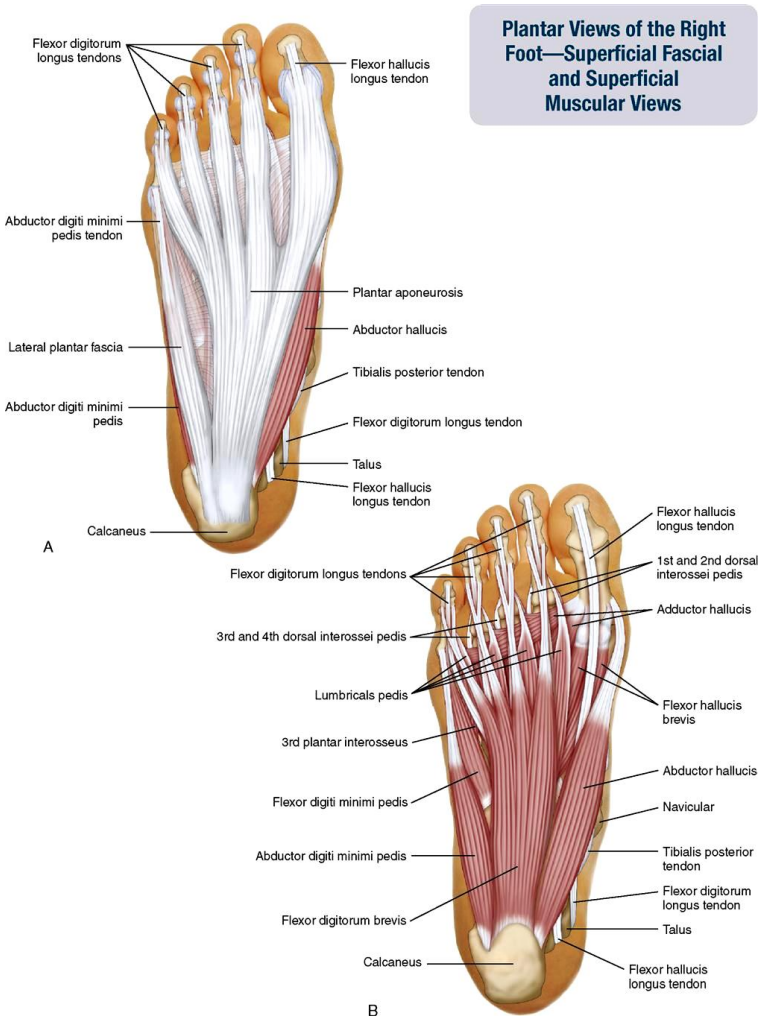
- Tibialis posterior,
- Flexor hallucis longus,
- Flexor digitorum longus.

INTRINSIC MUSCLES OF FOOT

It includes muscles of great toe,muscles of little toe and central group of intrinsic muscles.

Muscles of great toe includes,

- Abductor hallucis brevis,
- Flexor hallucis brevis,
- Adductor hallucis brevis.



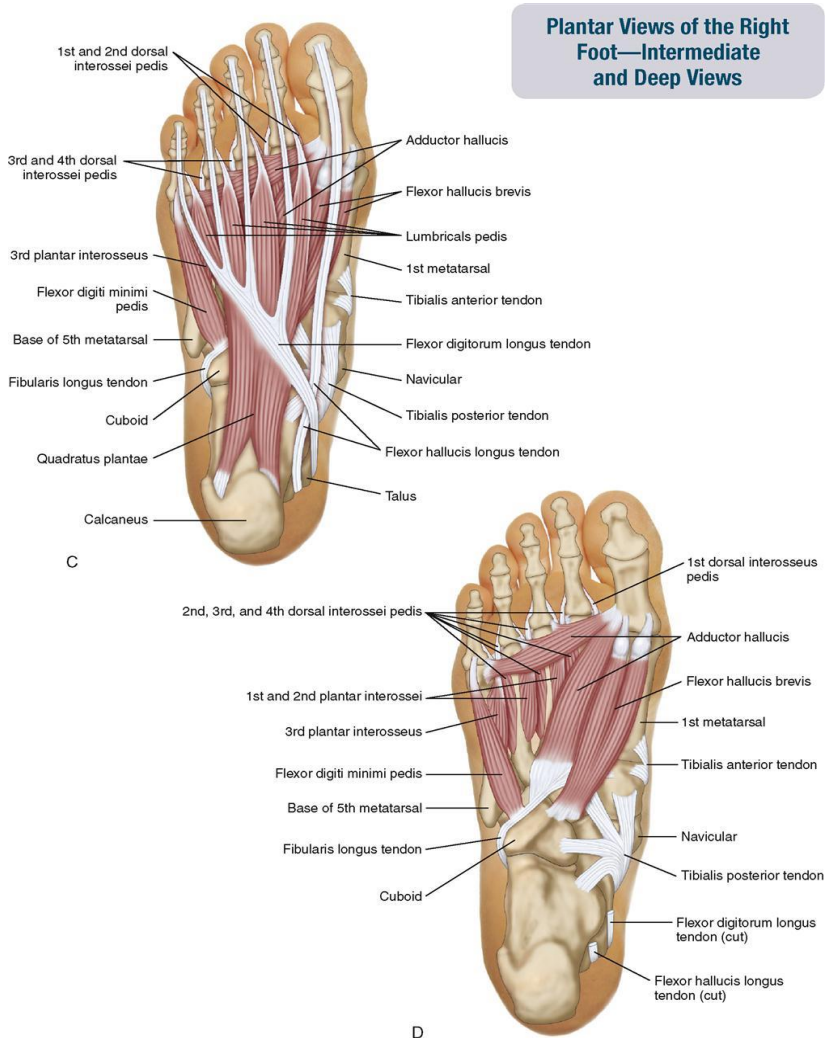
Muscles of little toe comprises of,

- Abductor digiti minimi,
- Flexor digiti minimi,
- Opponens digiti minimi.

Central group of muscles includes,

- Four lumbricals,

- Quadratus plantae,
- Flexor digitorum brevis,
- Dorsal interossei,
- Plantar interossei.



BLOOD SUPPLY OF FOOT

Plantar aspect being supplied by

Medial plantar artery,

Lateral plantar artery,

Plantar arch,

Plantar metatarsal artery.

Dorsum of foot being supplied by

Dorsalis pedis artery,

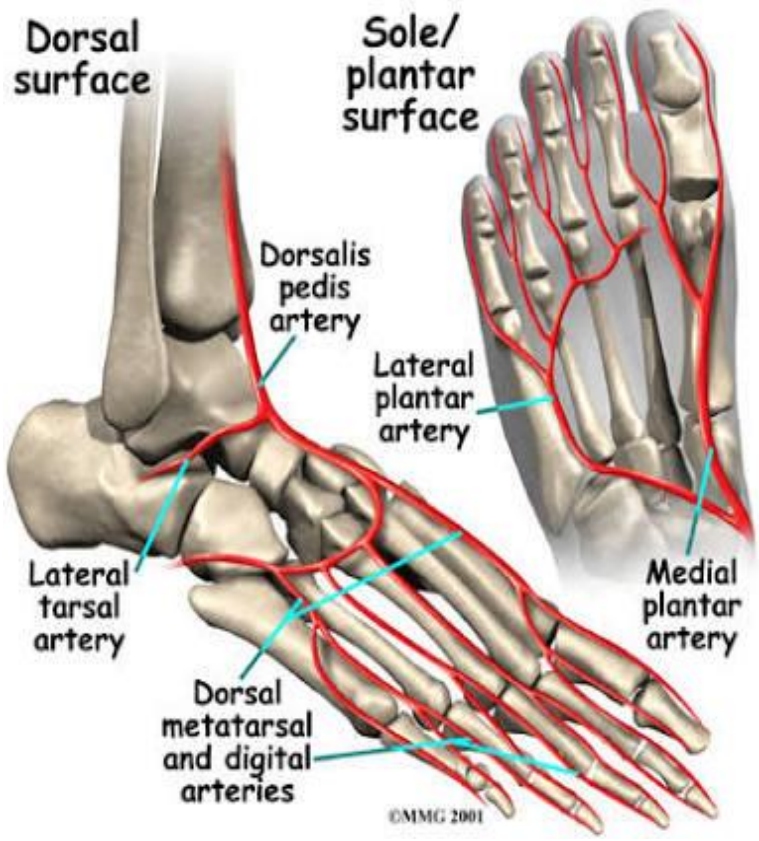
First dorsal metatarsal artery,

Medial tarsal artery,

Lateral tarsal artery,

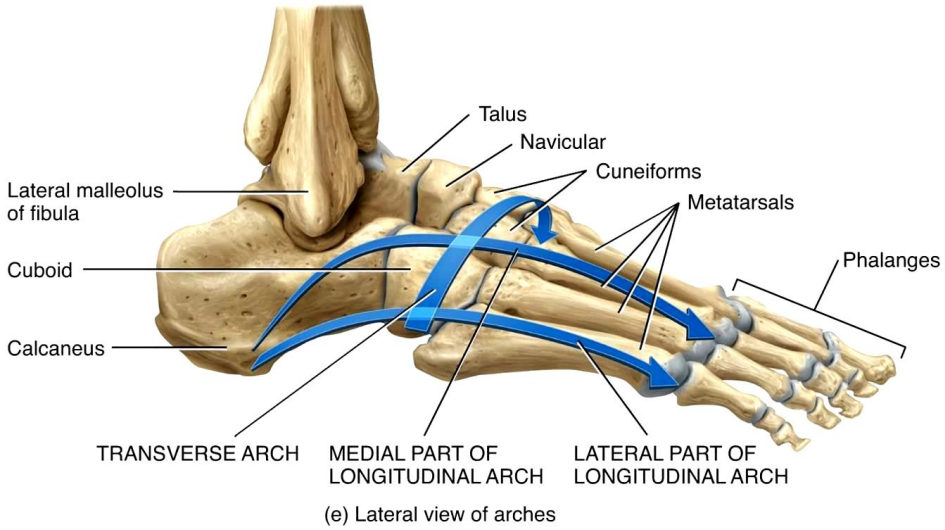
Arcuate artery,

Dorsal metatarsal artery.



ARCHES OF FOOT

It is composed of two longitudinal arches and one tranverse arches



Longitudinal arches of foot are composed of medial and lateral ones.

Medial longitudinal arch is the highest arch and is more mobile and is formed by heads of 1st and 2nd metatarsals ,medial tubercle of calcaneum. It is the shock absorber of foot.

Lateral longitudinal arch is lower than the medial arch and is formed by heads of 4th and 5th metatarsals and lateral tubercle of calcaneum. It transmits weight and thrusts to the ground.

Transverse arches of foot are composed of anterior and posterior arches.

Anterior transverse arch is formed by heads of 5 metatarsals and it is a complete arch. Posterior transverse arch is formed by greater parts of talus and bases of metatarsals and it is an incomplete arch.

Arches of foot are maintained by shape of bones,intersegmental ties by ligaments and bowstrings by flexor hallucis tendon and slings by peroneus longus.

FUNCTIONS OF ARCHES

It distributes body weight to weight bearing areas of foot. It acts as a springs during walking and running. It acts as shock absorbers. It protects soft tissue of foot from pressure. Medial arch characters for resiliency. Lateral arch for rigidity.

BIOMECHANICS OF FOOT

It includes static and dynamic component. Static component of gait involves windlass effect of plantar aponeurosis,tensile strength of plantar ligaments, beam effect of metatarsals and joint congruity of tarsal and metatarsal bones.

Dynamic component of gait includes pronation and supination. Pronation constitutes foot strike to toe strike. Three muscles are active

Tibialis Anterior,

Extensor digitorum longus,

Extensor hallucis longus.

Supination component includes end of stance phase of gait. It acts as muscle pulley system by synergistic action of extrinsic and intrinsic muscles of foot.

CHANGES IN ARCHES OF FOOT IN DIABETES

Ischemia and neuropathy leads to muscle atrophy and stiffening,

Ligament stiffening due to deposition of glycation products,

Infection leads to destruction,

Osteoporosis,

Architectural change due to repeated trivial trauma,

Collapse of arches.

DEFORMITIES DUE TO FAILURE OF MAINTENNANCE OF ARCHES

Most common deformities includes

Pes cavus,

Hallux valgus,

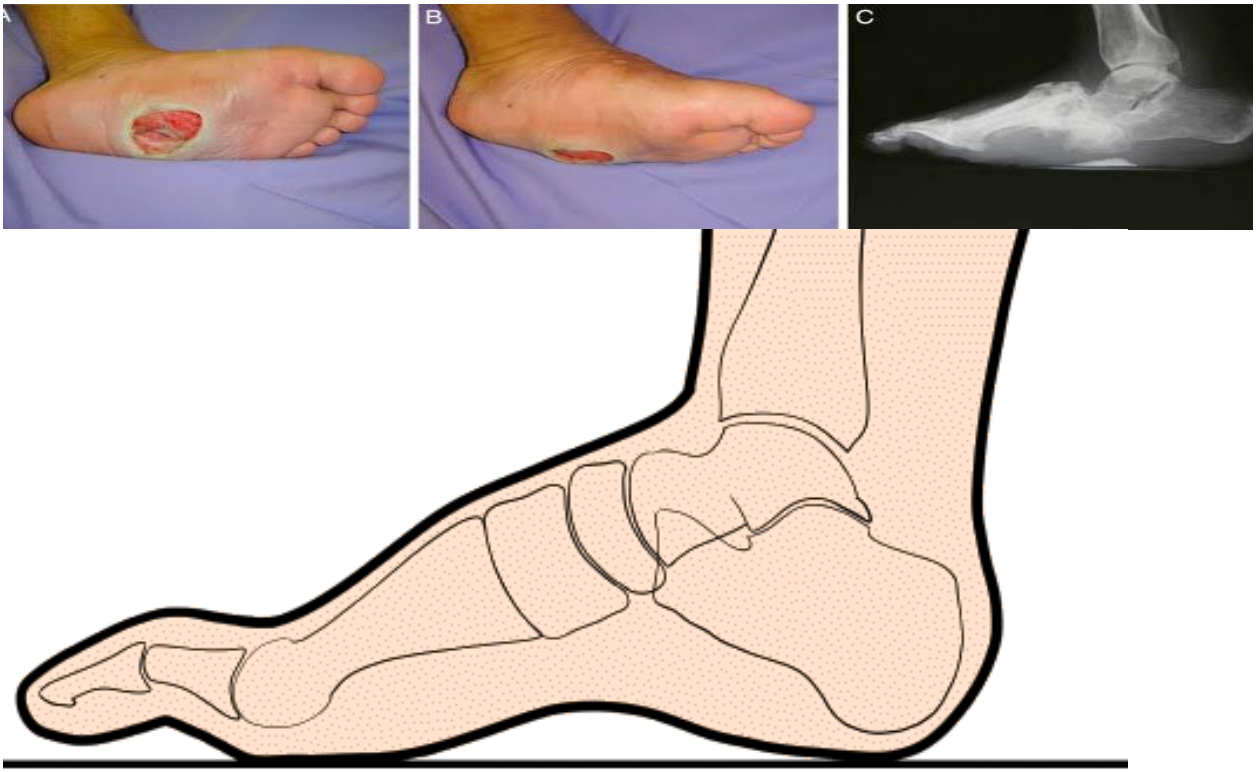
Charcot foot.

Pes cavus

Hallux valgus

, 

Charcot foot.



PATHOPHYSIOLOGY OF DIABETIC FOOT

Factors leading to development of diabetic foot,

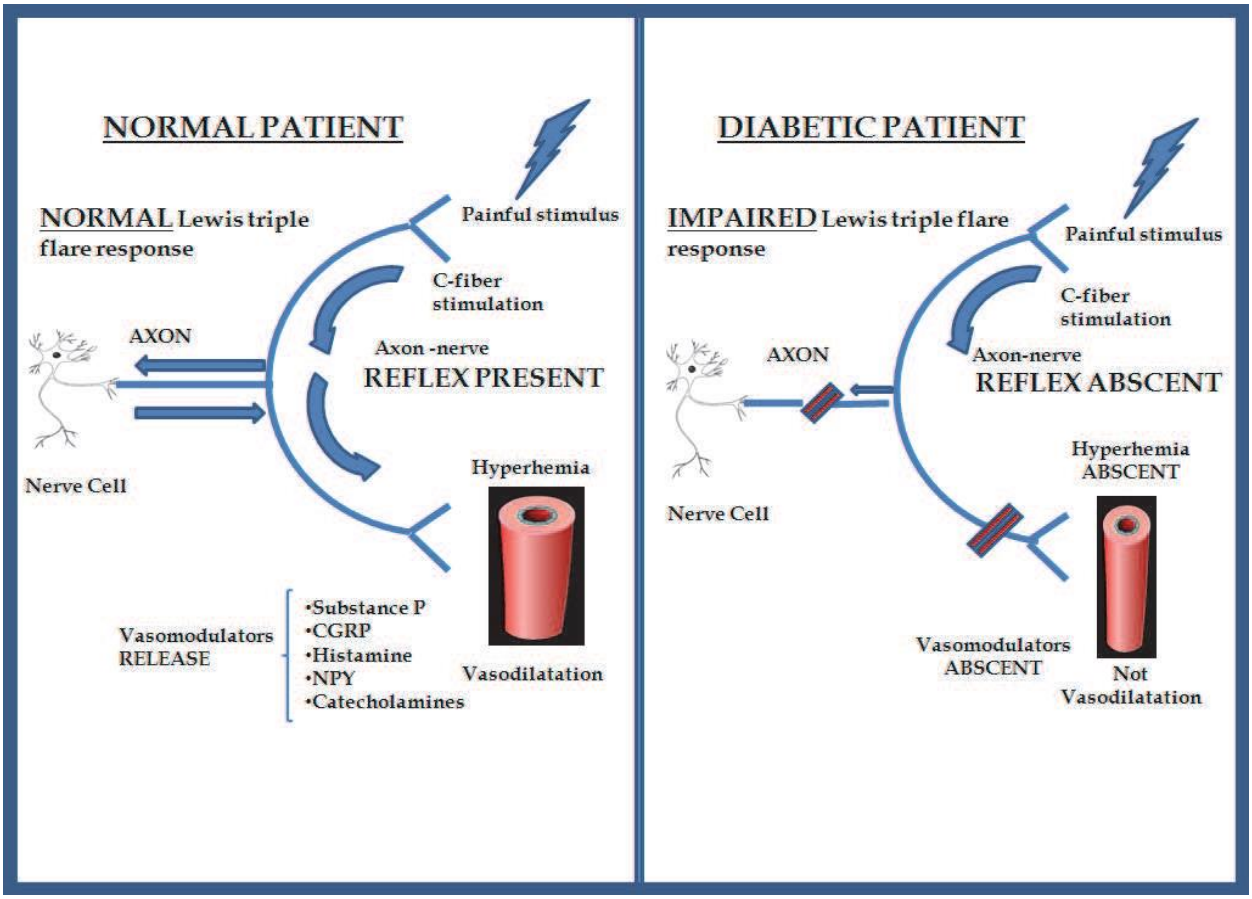
- Diabetic microangiopathy

  This is mainly due to thickening of basement membrane.

- Diabetic macroangiopathy

  This results in peripheral arterial occlusive diseases.

- Diabetic polyneuropathy
- Diabetic osteoarthropathy
- Increased glucose in tissues precipitates infection
- Increased glycosylated haemoglobin decreases oxygen dissociation
- Increased glycosylated tissue protein result in decreased oxygen utilization by tissues
- Diabetic neuropathy involving sensory,motor and autonomous components
- Reduced rate of collateral formation
- Associated atherosclerosis



Diabetic foot can be classified into two groups,

1.Neuropathic foot with palpable pulses,

2.Ischemic foot without pulses and a varying degree of neuropathy,

NEUROPATHIC FOOT

Warm ,bounding pulses and distended dorsal veins,

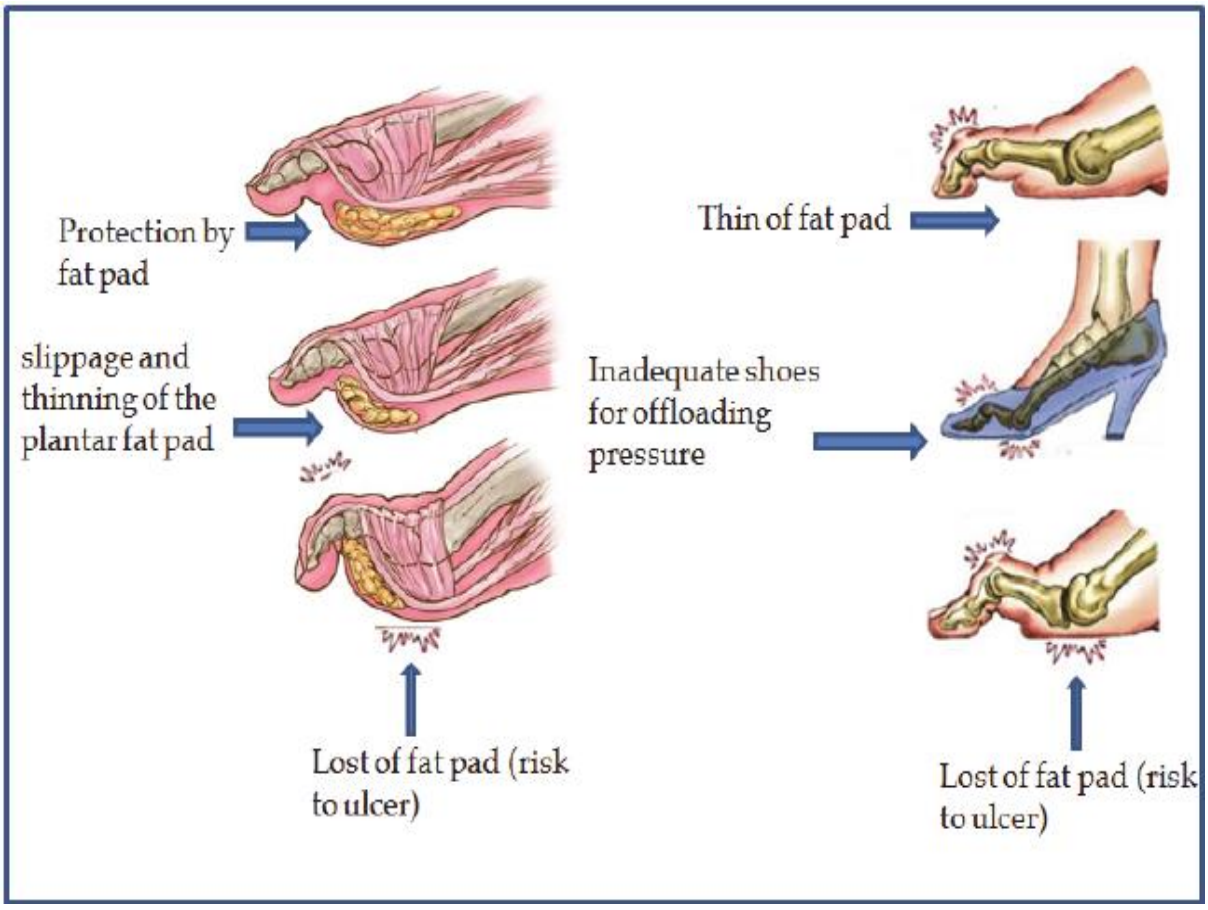
Diminished sweating,

Dry and fissuring foot,

Claw toes and foot arch raised,

Ulceration in sole.

Long standing neuropathic foot may develop into neuroischemic foot.



1.Motor neuropathy

High medial longitudinal arch,leading to prominent metatarsal heads and pressure points over the forefoot.

It may be related with claw toe and atrophy of the muscles.

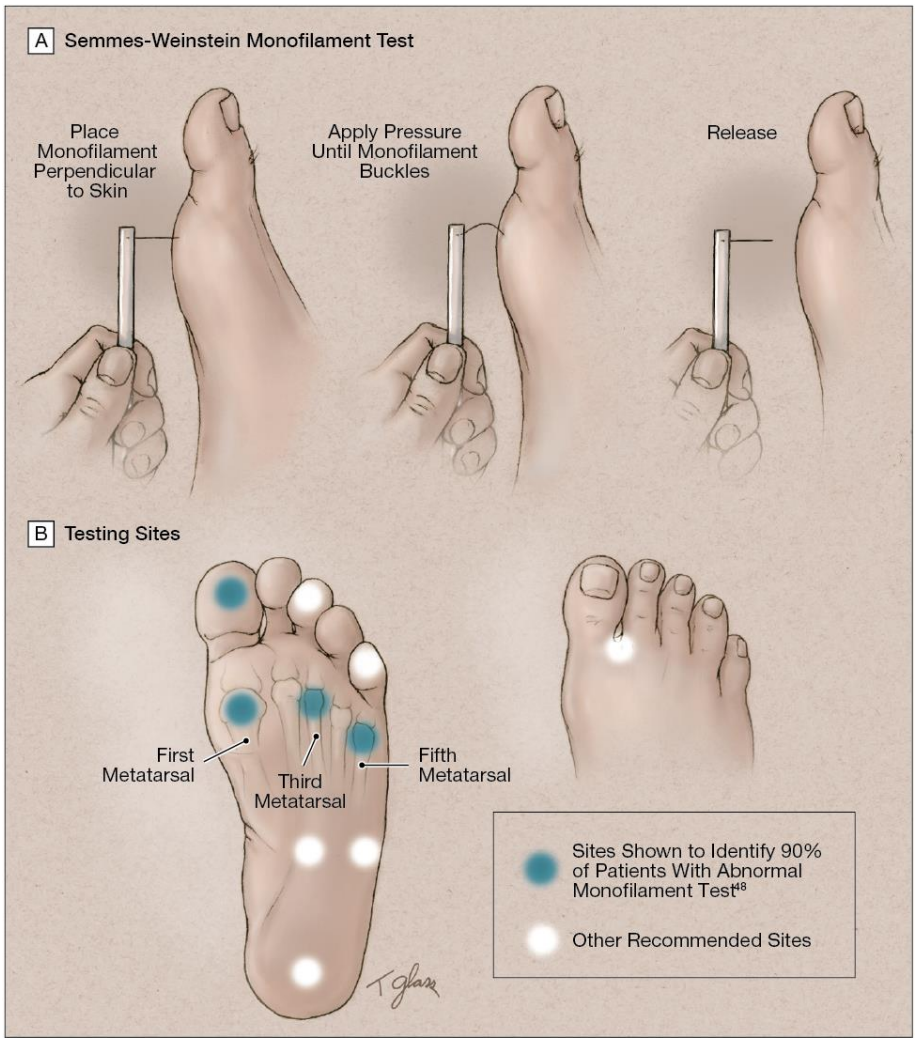
2.Autonomic neuropathy

Dry skin can lead to fissuring.

Distended veins over dorsum of foot and ankle.

3.Sensory neuropathy

SCREENING FOR NEUROPATHY



Inability to perceive 10 gm of force applied by the monofilament is associated with clinically significant large fiber neuropathy and an increased risk of ulceration.

For each of 8 stimuli,assign a score of

0 - Not perceived

0.5 - Less than that perceived on the forehead or sternum

1 - Perceived normally

A score of 3 correct response out of 8 means presence of neuropathy is more likely. A score of 3.5 to 5 means that the risk of new onset neuropathy in the next 4 years is high. A score of 5.5 or greater indicates low risk of neuropathy onset in the next four years.

ISCHEMIC FOOT

Cool ,pulselessfoot with decreased perfusion.

1.Neuroischemic foot

Ulceration is seen commonly on the margins of the foot,tips of toes and areas around back of heel.

Intermittent claudication and rest pain may be absent.



2. Critically ischemic foot

Presents as a pink often painful foot with pallor on elevating the foot and rubor on dependency

3.Acutely ischemic foot

Sudden pallor and foot becomes mottled

4.Renal ischemic foot

Classical feature of this foot is the digital necrosis.

CLASSIFICATION OF DIABETIC FOOT ULCER DISEASE

EDMOND'S CLASSIFICATION

Stage 1

Normal diabetic foot and the foot which is not at risk

Stage 2

High risk foot and in which risk factors for ulceration present.

Stage 3

Develops skin break down. Ulcers seen in plantar surface in neuropathic foot whereas ulcers occurs in margins in ischemic foot.

Stage 4

Developed infection with presence of cellulitis,which can complicate neuropathic and neuroischemic foot.

Stage 5

Necrosis has formed in the neuropathic foot. Infection is the most common reason for such tissue destruction eventhough ischemia contributes.

Stage 6

The foot cannot be saved ,when there is a need major amputation – unsalvageable foot

WAGNER CLASSIFICATION OF DIABETIC FOOT ULCERS

Grade 0

Preulcer stage

Skin is intact

Redness of skin

Callosities

Bony deformities

Grade 1

Superficial ulceration

Grade 2

Deep ulceration with visible tendons/bones.

Grade 3

Deep abscesses and osteomyelitis

Grade 4

Localized gangrene of toes or forefoot

Grade 5

Gangrene of entire foot or leg

STAGING SEVERITY OF INFECTION

Staging classification adopted by international consensus on diabetic foot and

Infectious Disease Society of America utilizes PEDIS acronym

P- Perfusion

E -Extent

D-Depth / tissue loss

I-Infection

S-Sensation

Clinical manifestation of infection	**PEDIS GRADE**	**IDSA SEVERITY**
No signs of infection	1	uninfected
>=2 manifestation of inflammation cellulitis<2cm , limited to skin or superficial sub cutaneous tissue	2	Mild
Cellulitis >2 cm,lymphangitic streaking , beyond subcutaneous layers Abscess , gangrene	3	Moderate
With systemic toxicity or metabolic instability	4	Severe

SINBAD CLASSIFICATION

Site,Ischemia,Neuropathy,Bacterial infection,Area of an ulcer,and Depth of an ulcer are taken into consideration.

Ulcer scored 0 (negative) or 1(positive) for each

Sum scores 0-6

Category	Definition	SINBAD Score
SITE	Fore foot	0
	Mid food and Hind foot	1
ISCHAEMIA	Pedal blood flow intact:atleast one pulse palpable	0
	Clinical evidence of reduced blood flow	1
NEUROPATHY	Protective sensation intact	0
	Protective sensation lost	1
BACTERIAL INFECTION	None present	0 1

AREA	Ulcer<1cms	0
	Ulcer>1cms	1
DEPTH	Ulcer confined to skin and subcutaneous tissue. Ulcer reaches muscle ,tendon ,or deeper.	0 1

KEY POINTS IN EACH OF DIABETIC ULCER DISEASE CLASSIFICATION

Classification system	Key points	pros /cons
Wagner	Assesses ulcer depth along with presence of gangrene and loss of perfusion	Well established Does not fully address infection and ischemia

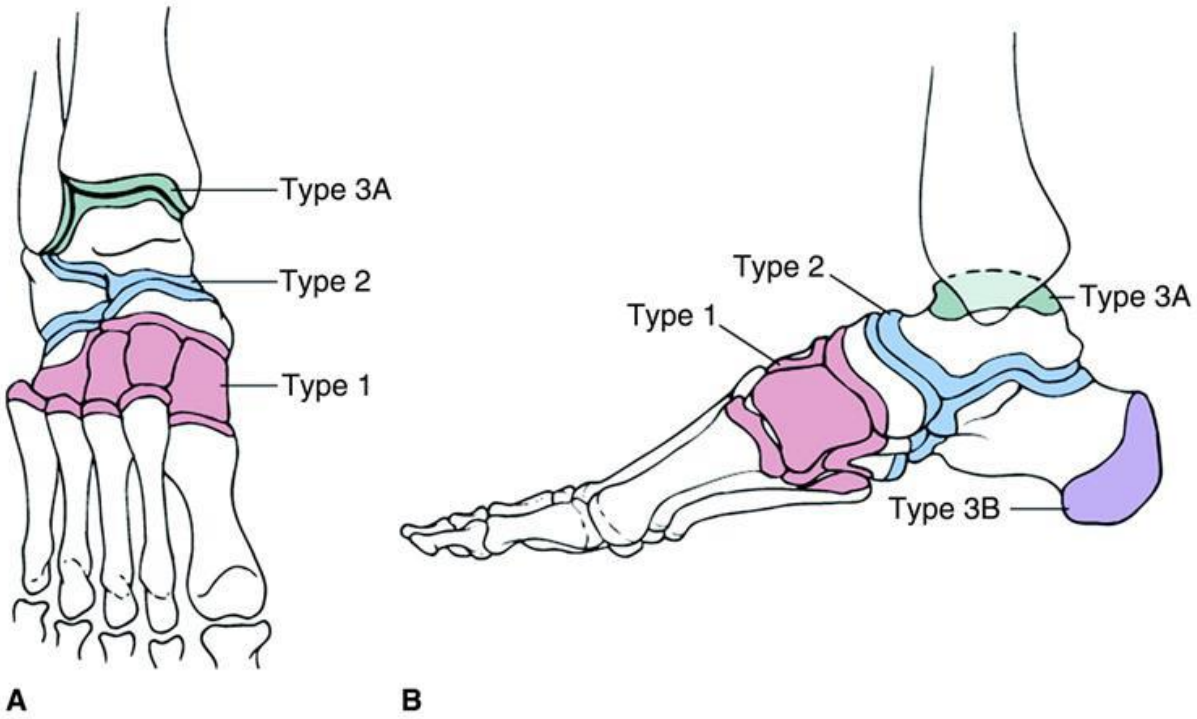
University of Texas	Ulcer depth ,presence of infection , and signs of lower extremity ischemia	Well established Describes presence of infection and ischemia better than Wagner ,predicting the outcome of the DFU
PEDIS	Perfusion ,extent ,depth ,infection ,and sensation	Developed by IWGDF User friendly for practitioners
SINBAD	Uses a scoring system to help predict outcomes	Includes ulcer site as data suggests this might be an important determinant of outcome

CHARCOT NEUROPATHY

A chronic and progressive joint disease following loss of protective sensation resulting in destruction of joints and surrounding bony structures.

It may lead to amputation if left untreated.

Brodsky Classification		
Type 1	• Involves tarsometatarsal and naviculocuneiform joints • Collapse leads to fixed rocker-bottom foot with valgus angulation	60%
Type 2	• Involves subtalar, talonavicular or calcaneocuboid joints • Unstable, requires long periods of immobilization (up to 2 years)	10%
Type 3A	• Involves tibiotalar joint • Late varus or valgus deformity produces ulceration and osteomyelitis of malleoli	20%
Type 3B	• Follows fracture of calcaneal tuberosity • Late deformity results in distal foot changes or proximal migration of the tuberosity	< 10%
Type 4	• Involves a combination of areas	< 10%
Type 5	• Occurs solely within forefoot	< 10%



Based on xray radiographic findings charcot neuropathy can be staged as follows:

Eichenholtz Classification		
Stage 0		• Joint edema • Radiographs are negative • Bone scan may be positive in all stages
Stage 1	fragmentation	• Joint edema • Radiographs show osseous fragmentation with joint dislocation
Stage 2	coalescence	• Decreased local edema • Radiographs show coalescence of fragments and absorption of fine bone debris
Stage 3	reconstruction	• No local edema • Radiographs show consolidation and remodeling of fracture fragments

DEFORMITIES OF TOES AND NAILS

Onychogryphosis

It is also known as Ram's horn nails. It's the hypertrophy that may produce nails resembling claws or a ram's horn.

Onychocryptosis

It is ingrowing of toe nail.

Treatment

Partial nail avulsion followed by phenolization or direct surgical excision of nail matrix. Both of the treatment are equally effective.

Onychomycosis

Fungal infection can cause whitish or yellowish discolouration of nail plate.

Treatment

Oral antifungals such as itraconazole and terbinafine are being used.

Efinaconazole can be used topically.

Removal of nail plate should be considered as an adjuvant treatment in patients undergoing oral therapy.

Subungual haematoma

It causes trauma to nail , blood collects under nail. It can be drained by making small hole in the nail plate.

Claw toes

Conservative measures such as shoe with deep soft toe box and silicon rubber orthotics can be used.

Surgical management includes arthroplasty of the proximal interphalangeal joint can be performed.

Hammer toes

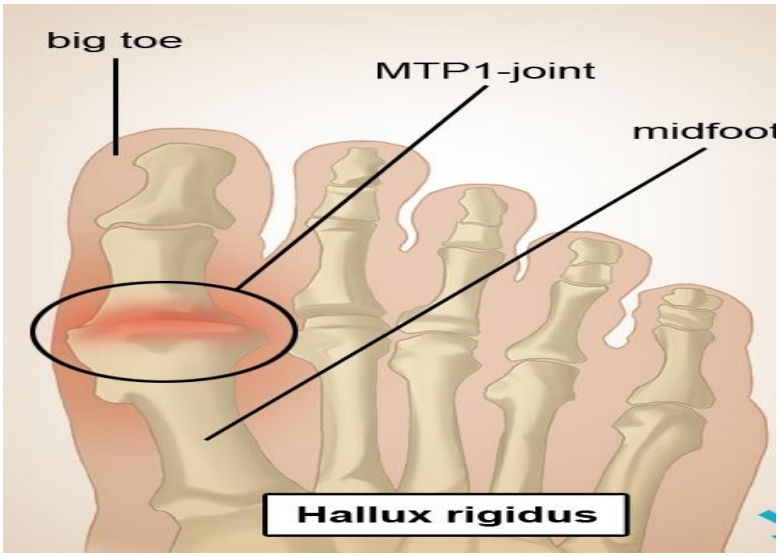
Conservatively splints and shoe with wide deep toe box can be applied.

If there is a fixed deformity , Arthroplasty of the proximal interphalangeal joint can be performed. The position of the toe can be maintained with a kirschner wire.

Mallet toes

Surgical management includes distal interphalangeal joint Arthroplasty

Hallux rigidus



Two surgical options available are hallux interphalangeal joint arthroplasty or keller's resectional arthroplasty of the first metatarsophalangeal joint.

Hallux valgus

Splints and shoe with wide toe box can be applied as a conservative measure. Surgical management includes keller's resectional arthroplasty .

In case of diabetic foot ulcers presenting with any gangrenous changes, Ankle Brachial index has to be measured to confirm ischaemia.

Doppler study of both lowerlimbs to identify any vascular compromise.

1.Pressure index o.5

2.Doppler waveform triphasic,damped

3.Transcutaneous o2 tension <30 mm hg

4.Toe pressure <30 mm hg

If all the above measurements are observed ,then angiography followed by angioplasty can be done. Statins and cilastazole therapy has to be initiated

If the following findings are observed in ulcer case,then it is indicative of infection :

1.>2cm surrounding redness

2.local inflammatory changes

3.Increased pain

4.Friable granulation tissue

5.wound breakdown

6.Increased exudate secretion

7.Foul smelling odour

8.Probe into the bone.

SIGNS OF A HEALING ULCER

1.Ulcer bed becomes pink,shiny,glistening granulations

2.Ulcer decreases in size and depth

3.Formation of new epithelium around the edges

4.Ulcer dries with less discharge

5.Swelling diminishes

6. Less painful

7.smell ceases and no undermining edges.

SIGNS OF DETERIORATION

1.Unfavourable colour of ulcer bed

2.Dimension of ulcer becomes static or increases

3.Local swelling develops/increases

4.Foot becomes painful

5.Foul smelling odour develops

6.Undermined edges

DEBRIDEMENT

Removal of callus and dead tissue thereby stimulates healing and drainage of exudates.

CULTURE

For clinically unifected wounds , collecting a specimen for culture is no recommended.

For infected wounds,appropriate specimens for culture should be obtained prior to starting empirical antibiotic therapy.

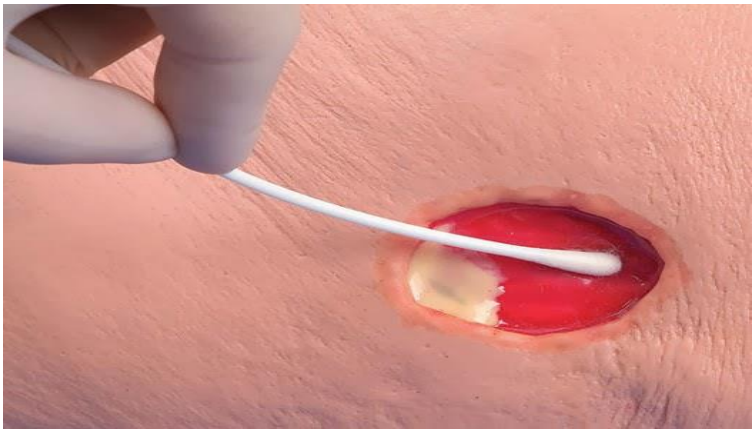
Various methods available are swab,tissue biopsy,needle aspiration.

SWAB

Levine's method

Clean the wound with normal saline to avoid surface contamination. Debride eschar,slough before culturing.

Place the swab on the most symptomatic area. Rotate and press down to express fluid from viable tissue for one square.centimeter area. Recap the tube by no touch technique. Transport to lab <24 hrs.



TISSUE BIOPSY

The most preferred method of collecting specimen for culture. Wound must be cleaned with sterile normal saline /water. Atleast one sq.cm of viable tissue should be taken. It should be transported to culture medium <24 hrs.

Avoid pus and necrotic material as it may give false results. Curettings and scrapings from base can be sent. Deep tissues from operative debridement is better than a swab. Bony fragments from debridement can be sent.

BLOOD GLUCOSE LEVELS FOR DIAGNOSIS OF DIABETES AND PRE DIABETES

	HbA1c (percent)	Fasting Plasma Glucose (mg/dL)	Oral Glucose Tolerance Test (mg/dL)
Diabetes	≥ 6.5	≥ 126	≥ 200
Prediabetes	5.7 – 6.4	100 - 125	140 – 199
Normal	~ 5.7	≤ 99	≤ 139

MICROBIOLOGY

Diabetic foot ulcers are polymicrobial.

- Gram positive
  - Staphylococcus aureus
  - ß-haemolytic Streptococcus
  - Enterococcus

- Gram negative
    - Pseudomonas
    - Proteus
    - Klebsiella
    - E.coli
- Anaerobes
    - Bacteriodes
    - Clostridium
    - Peptostreptococcus

ROLE OF TOPICAL ANTIMICROBIALS

- Reduced antibiotic tissue penetration — for example, where the patient has a poor vascular supply
- In non-healing wounds where there is a clinical suspicion of increased bacterial bioburden.
- Topical antimicrobials have the potential to reduce bacterial load and may protect the wound from further contamination.
- Advantages
    - not driving resistance.
    - provide high local concentrations.

- Disadvantages
    - Do not penetrate intact skin or into deeper soft tissue.
- They should be combined with systemic antibiotics , if there is clinical signs of infection .

TOPICAL ANTIMICROBIALS

- Silver
- Fusidic acid
- Polyhexamethylene biguanide (PHMB)
- Iodine

PRINCIPLES OF ANTIBIOTIC SELECTION

- Diabetic ulcers are Polymicrobial .
- Diabetic patients are immunocompromised, even skin commensals cause severe tissue damage.
- Start empirical therapy because
    - Difficult to interpret the organism from clinical presentation.
    - Neuropathy and ischemia reduces resistance for local invasion.

SUPERFICIAL DIABETIC FOOT ULCERS WITH SKIN INFECTION

- Start oral antibiotic therapy targeted at Staphylococcus aureus and beta haemolytic Streptococcus.
- Change to an alternate antibiotic based on the culture.

DEEP TISSUE INFECTION

It includes cellulitis, lymphangitis, septic arthritis, fasciitis.

- Start patients on broad-spectrum antibiotics without waiting for culture.
- Culture deep tissue specimens or aspirates.
- Change to an alternate antibiotic
    - according to microbiology results.
    - If the signs of inflammation are not improving.

DURATION OF THERAPY

- Duration should be based on
    - the severity of the infection,
    - the presence or absence of bone infection,
    - clinical response to therapy.
- 1–2 weeks for skin and soft tissue infections.
- Antibiotics can usually be discontinued once the clinical signs and symptoms of infection have resolved.

DRESSING

It protects the wound from noxious stimuli.

It keeps the wound warm.

It reduces the infection.

It prevents from insect infestation

Ideal wound dressing should be,

- Sterile, easy to use, cost effective ,
- Maintain a moist wound healing environment,
- Absorb excess exudates,
- Non-adherent/non-toxic, non-allergic,
- Not contaminate the wound with foreign particles,
- Protect the wound from microorganisms,

- Allow gaseous exchange and control wound odor,
- Provide thermal insulation and mechanical protection.

The most commonly used cleansing agents is normal saline.Along with it, conventionally used antimicrobials are iodine,hydrogen peroxide.

IODINE

- Antimicrobial action
- Two types
- Povidone iodine- effective in antibiotic propylaxis
- Cadexomer- consists of microsphere of cross linked starch chains
- Decreases bacterial load

HYDROGEN PEROXIDE

It liberates oxygen and it is used for sloughy and necrotic wounds.

TYPES OF DRESSINGS

- Low adherence dressing
- Alginate
- Polyurethane foams
- Honey impregnated dressing
- Hydrogel/colloid dressing
- Polyurethane films
- Iodine /silver impregnated dressing

GLYCEMIC CONTROL

The main aim of diabetic management is to restore the carbohydrate metabolism to a normal state . This has been achieved by insulin replacement therapy in individuals with absolute deficiency of insulin and in case of insulin resistance ,it can be achieved by dietary modifications and exercises.

Insulin resistance may be acute or chronic. In acute cases, it develops rapidly and is usually a short term problem. It can be precipitated by

- Infection
- Trauma
- Stress
- Surgery
- Corticosteroids
- Ketoacidosis

Ketone bodies and free fatty acids inhibit glucose uptake by brain and muscle .Insulin binding may increase.

In chronic cases, common in type 2 diabetes mellitus where patients are treated for years with conventional preparations of beef or pork insulin. Antibodies to homologous proteins are produced and bind to insulin ,thus very high insulin resistance may be produced. By switching over to more purified newer insulin preparations, glycemic control can be achieved.

INDICATIONS FOR AMPUTATION

- When there is a massive reduction in arterial perfusion leading to necrosis that spreads up the foot
- Overwhelming infections destroying the localized site
- Severely ischaemic painful foot that cannot be revascularised and whose pain is difficult to control
- Unstable inoperable charcot hindfoot where external and internal fixation is not possible.

While choosing appropriate level of amputation the following points to be considered,

- Ensure sufficient perfusion of the residual stump
- Distal amputation to be done whenever possible
- Preserve knee joint whenever possible so as to reduce energy expenditure during walking.

The aim of amputation are

- Keep the amputation as distal as possible
- To amputate above painful,cold pale discoloured tissue
- To amputate below warm,pink well perfused tissue.

DIABETIC FOOT ULCERS WITH OSTEITIS

Ray amputation

Amputation of toe with head of metatarsal or metacarpals.

Gille's amputation

Transmetatarsal amputation. Here amputation is done proximal to neck of metatarsals,distal to the base.

Lisfranc's amputation

Tarsometatarsal amputation. Tarsometatarsal joint is disarticulated with a long volar flap

Chopart's amputation

Mid tarsal amputation. Talonavicular joint and calcaneocuboid joints are disarticulated. Tibialis anterior is sutured to talus bone. Long volar flap is used.

Syme's amputation

Removal of foot with calcaneum and cutting of tibia and fibula above the malleoli ,just above the ankle joint with retaining heel flap.

Below knee amputation

Long posterior flap with scar placed over anterior aspect. Stump length is 14-17 cm from knee joint. Minimum length required for prosthesis is 8 cm.

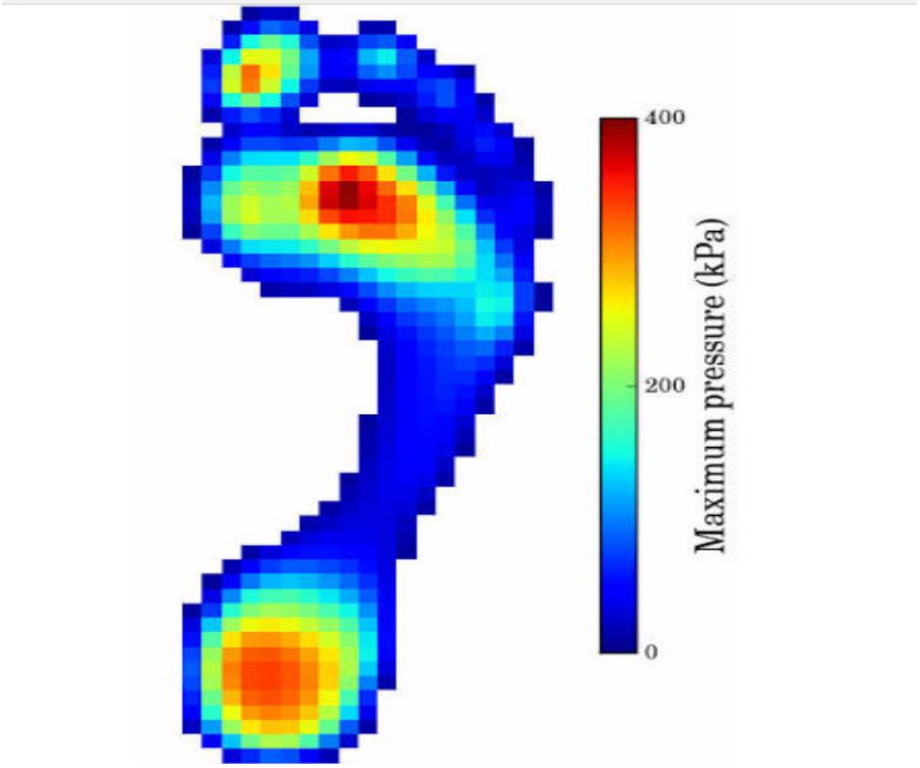
Above knee amputation

Equal anterior and posterior flaps are used. Ideally required length of femur as stump is 25cm from tip of trochanter.

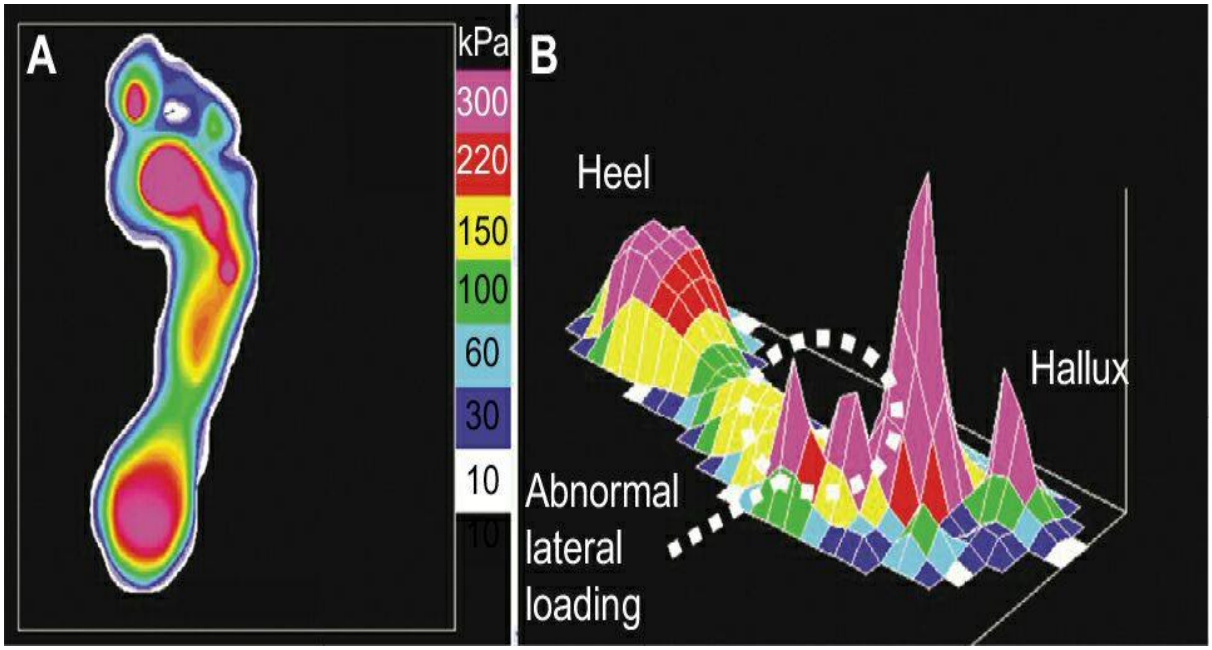
OFFLOADING

It is defined as redistribution of pressure off the wound to the entire weight bearing surface of foot.

Plantar foot pressure in a normal foot moves from heel to the toe through the midfoot and metatarsals.



PEAK PRESSURE PROFILE FOR DIABETIC FOOT



- Reduction of pressure and shear forces on the foot may be the single important and most neglected aspect of treating neuropathic ulceration.
- Off loading therapy is a key part of the treatment plan for diabetic foot ulcers.
- The goal is to off load the pressure at the ulcer while keeping the patient ambulatory.

MATERIALS AND METHODS

DESIGN OF STUDY:

Prospective study

PERIOD OF STUDY:

1 year

COLLABORATING DEPARTMENT:

Nil

SAMPLE SIZE:

60 patients are enrolled for the study after obtaining valid consent

SELECTION OF STUDY SUBJECTS:

Diabetic patients presented to surgical OPD with plantar foot ulcers in Government Rajaji Hospital, Madurai, satisfying the inclusion criteria were recruited for this study after obtaining valid consent.

ETHICAL CLEARANCE:

Obtained

CONSENT:

Individual written and informed consent

CONFLICT OF INTEREST:

None

FINANCIAL SUPPORT:

Nil

PARTICIPANTS:

Diabetic patients presented to surgical OPD with plantar foot ulcers in Government Rajaji Hospital, Madurai, satisfying the inclusion criteria were recruited for this study after obtaining valid consent.

INCLUSION CRITERIA

1. Diabetic patients with plantar ulcers (forefoot/midfoot/hindfoot),
2. Patients with wagner ulcer grading 2 or 3,
3. Patients with palpable peripheral pulses,
4. Patients consented for inclusion in the study according to designated performa.

EXCLUSION CRITERIA

1. Patients with wagner ulcer grade 4 or 5,
2. Patients with lowerlimb edema,
3. Patients requiring assistive device for unstable motility,
4. Patients not consented for inclusion in the study.

STUDY DESIGN

This is a prospective study on healing of Diabetic plantar foot ulcers treated with conventional measures alone vs conventional measures along with bohler iron plaster cast.

BOHLER IRON PLASTER CAST

It incorporates orthotic metal upright with rubber heel footplate with cast and a window over ulcer site.

STUDY PLACE

Department of General Surgery,

Madurai Medical College,

Madurai.

PROCEDURE

The patients are seen in surgical OPD routine hours and were diagnosed on the basis of history, clinical examination and investigations like Doppler.

In one group of subjects, the ulcer is debrided conventionally, until healthy tissue is encountered, if pus is present ,appropriate antibiotics are given. Patients were taught home dressing which has to be done daily & foot care education imparted to unaffected foot.

i.e., avoidance of bare foot walking, daily foot inspection, hygiene, proper trimming of nails.

In another group of subjects ,ulcer is managed conventionally with debridement , antibiotics and dressings, along with it a Bohler Iron Plaster Cast being used as an offloading device.

In case of Bohler Iron cast,Casting procedure begin with covering soft cotton roll adequately to protect the skin, particularly over bony prominences and plaster of paris cast applied from below knee upto sole of foot .The toes are left free. A window is left in the cast boot at the ulcer site to allow daily wound care by conventional measures. A bohler iron upright placed over cast on medial and lateral border of leg & over the heel and it incorporates a rubber heel foot plate one and half inch away from foot. Roller bandage applied over bohler iron to secure it in place.One inch heel raise given to contralateral foot (as half inch compensated in gait during foot clearance).

Subjects are evaluated twice i.e., before and after 1 month in both the groupsA questionnaire which included history,clinical examination, pressure ulcer scale for Healing (PUSH) are used in both.

PRESSURE ULCER SCALE FOR HEALING (PUSH)

Length * Breadth (cm^2) .a	**0** **0**	**1** **<0.3**	**2** **0.3 – 0.6**	**3** **0.7-1.0**	**4** **1.1-2.0**	**5** **2.1-3.0**
		6 3.1-4.0	7 4.1-8.0	8 8.1-12.0	9 12.1-24	10 >24.0
Exudate Amount.b	0 None	1 Light	2 Moderate	3 Heavy		
Tissue Type.c	0 Closed	1 Epithelial tissue	2 Granulation tissue	3 Slough	4 Necrotic tissue	

Total PUSH Score = A+B+C

Max.score = 17 (Not healed)

Min.score = 0 (completely healed)

Thus, by means of pressure ulcer scale for healing (PUSH) scores , we can assess the healing of ulcer. Higher the score ,ulcer is not healing and lower the score ,ulcer is healing well.

RESEARCH HYPOTHESIS

Offloading of foot by means of bohler iron plaster cast in diabetic foot ulcers will result in pressure dispersion from ulcer site , moreover it offloads the entire foot , not only the ulcer site. Thus in management of diabetic plantar foot ulcers by conventional measures along with bohler iron cast will hastens healing process.

STATISTICAL ANALYSIS

Study sample - 60

Participants are randomized into two groups

Group A - Conventional measures alone

Group B - Conventional measures with Bohler Iron Plaster Cast

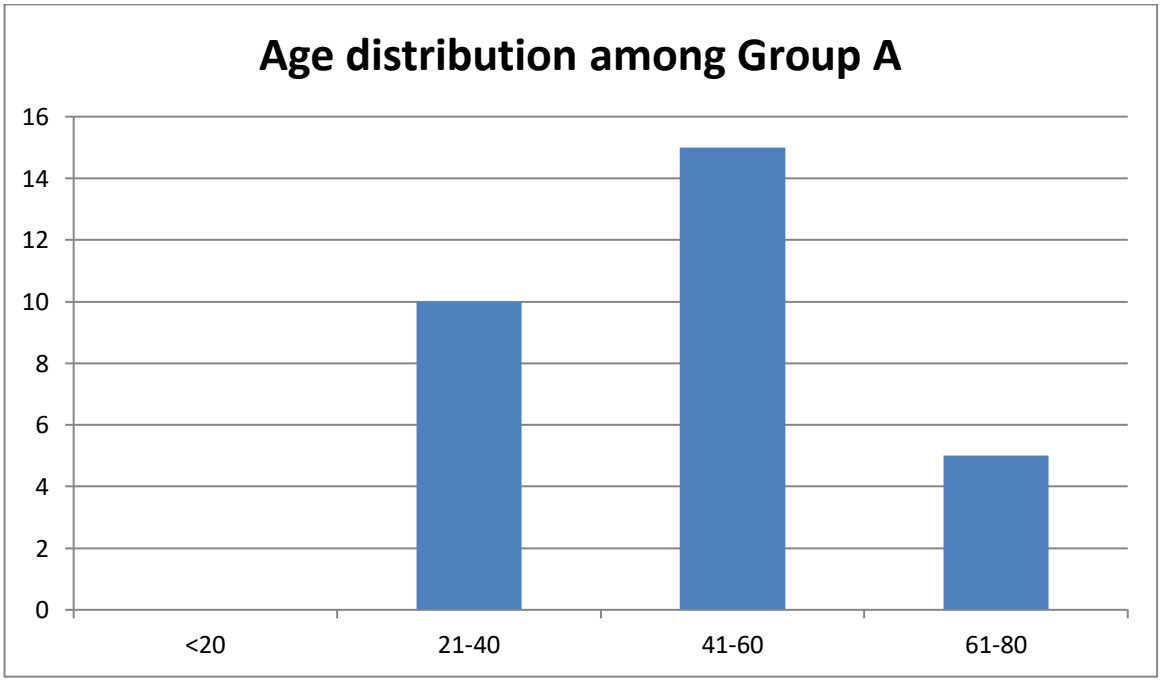
Paired test is used to compare Pressure ulcer scale for healing scores of each group before and after 1 month of intervention.

RESULTS

AGE AND GENDER DISTRIBUTION

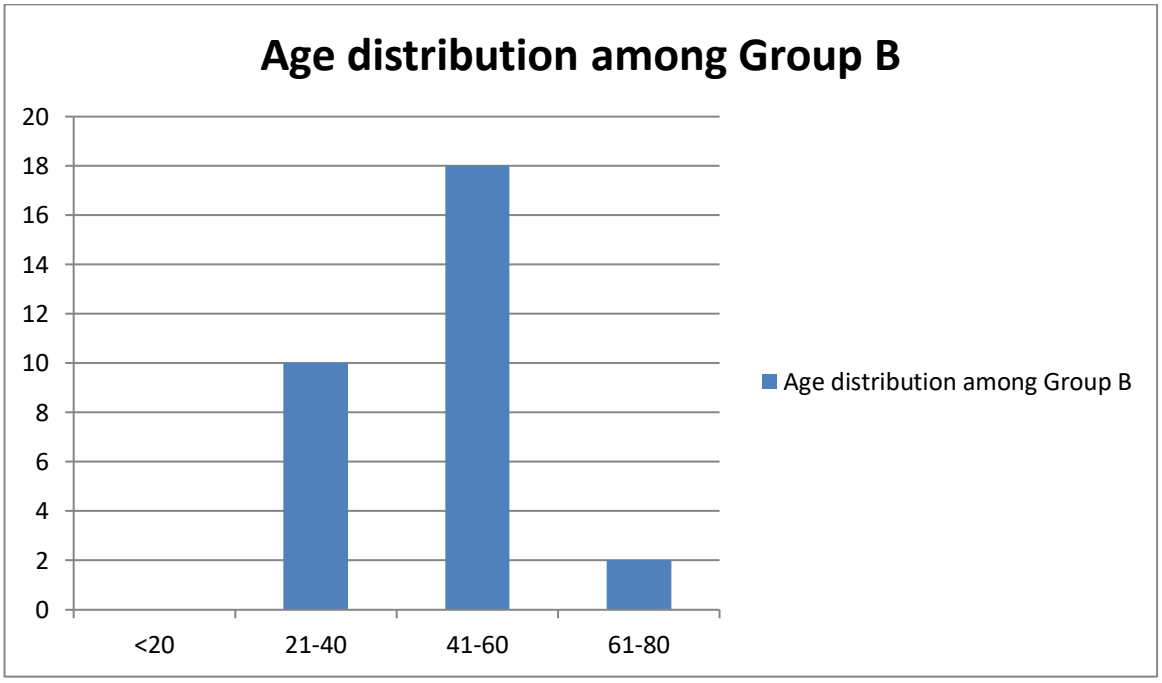
The following table shows age distribution among group A.

Age group	No.of cases
<20	0
21-40	10
41-60	15
61-80	5



The following table shows age distribution among group B.

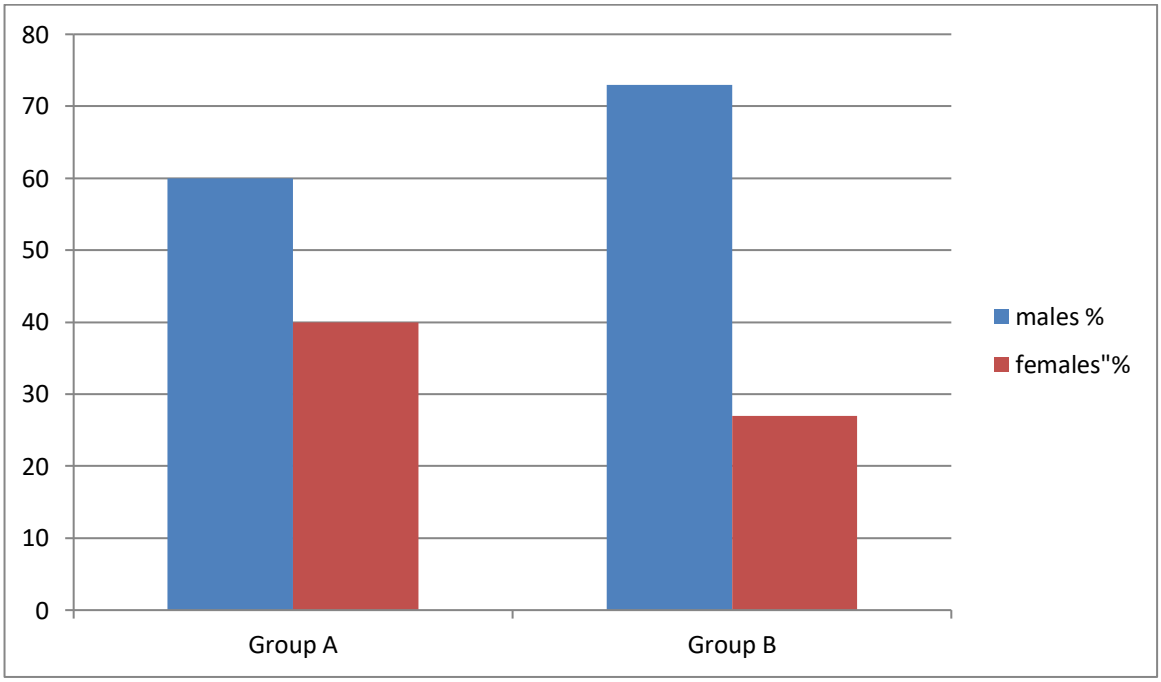
Age group	No.of cases
<20	0
21-40	10
41-60	18
61-80	2



The following table shows the gender distribution among Group A and Group B.

	Males (%)	Females(%)
Group A	60	40
Group B	73	27

GENDER DISTRIBUTION AMONG GROUP A AND GROUP B



Outcomes are measured based on the Pressure Ulcer Scale for Healing in Group A and Group B. Out of the 60 patients , none of the patients developed any new ulcers .

There was a good ulcer healing evidenced by significant reduction in the mean Pressure Ulcer Scale for Healing score after 1 month of intervention .

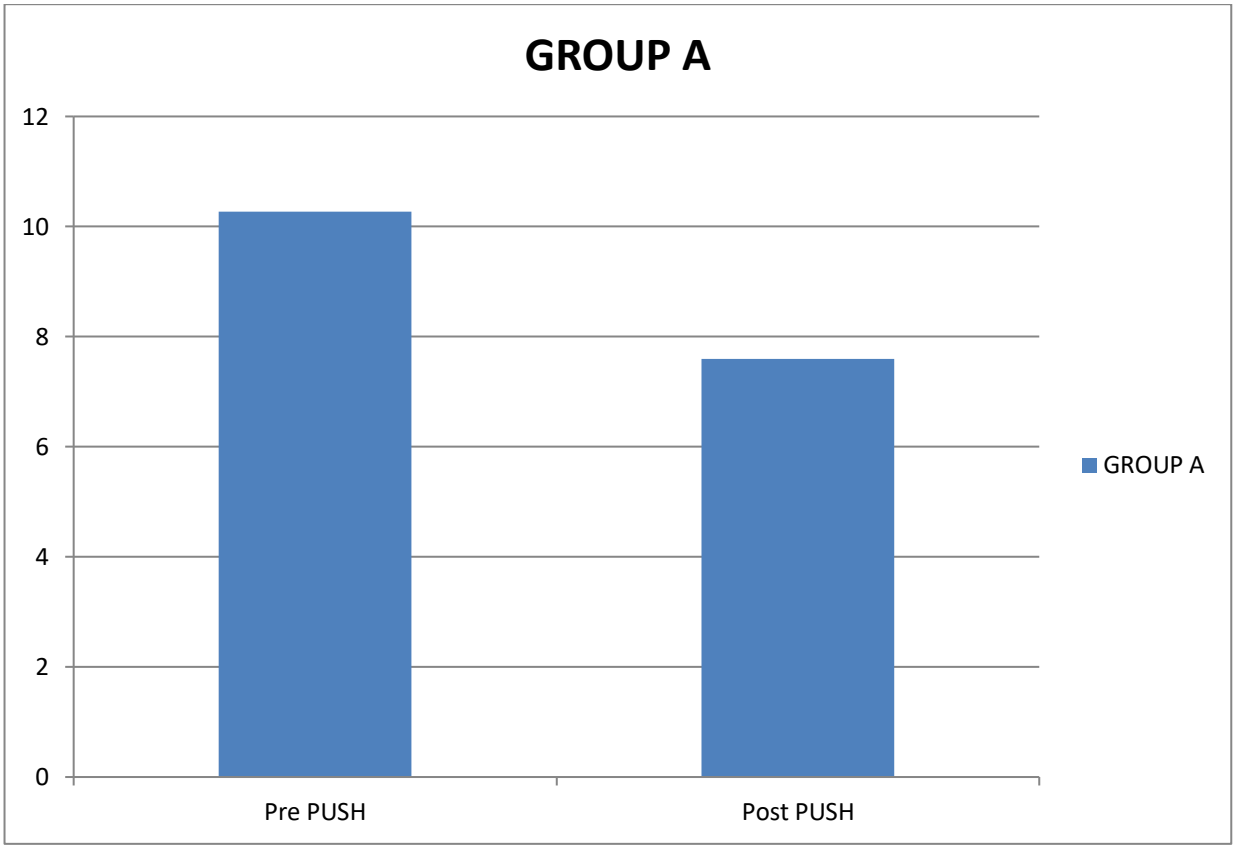
There is a statistical difference as the mean of pre-PUSH score of 10.27 is greater than Post-PUSH score 7.60 in the group A and the mean of Pre-PUSH score 8.65 is greater than post PUSH score 5.93 in the group B.

DISCUSSION OF THE STUDY

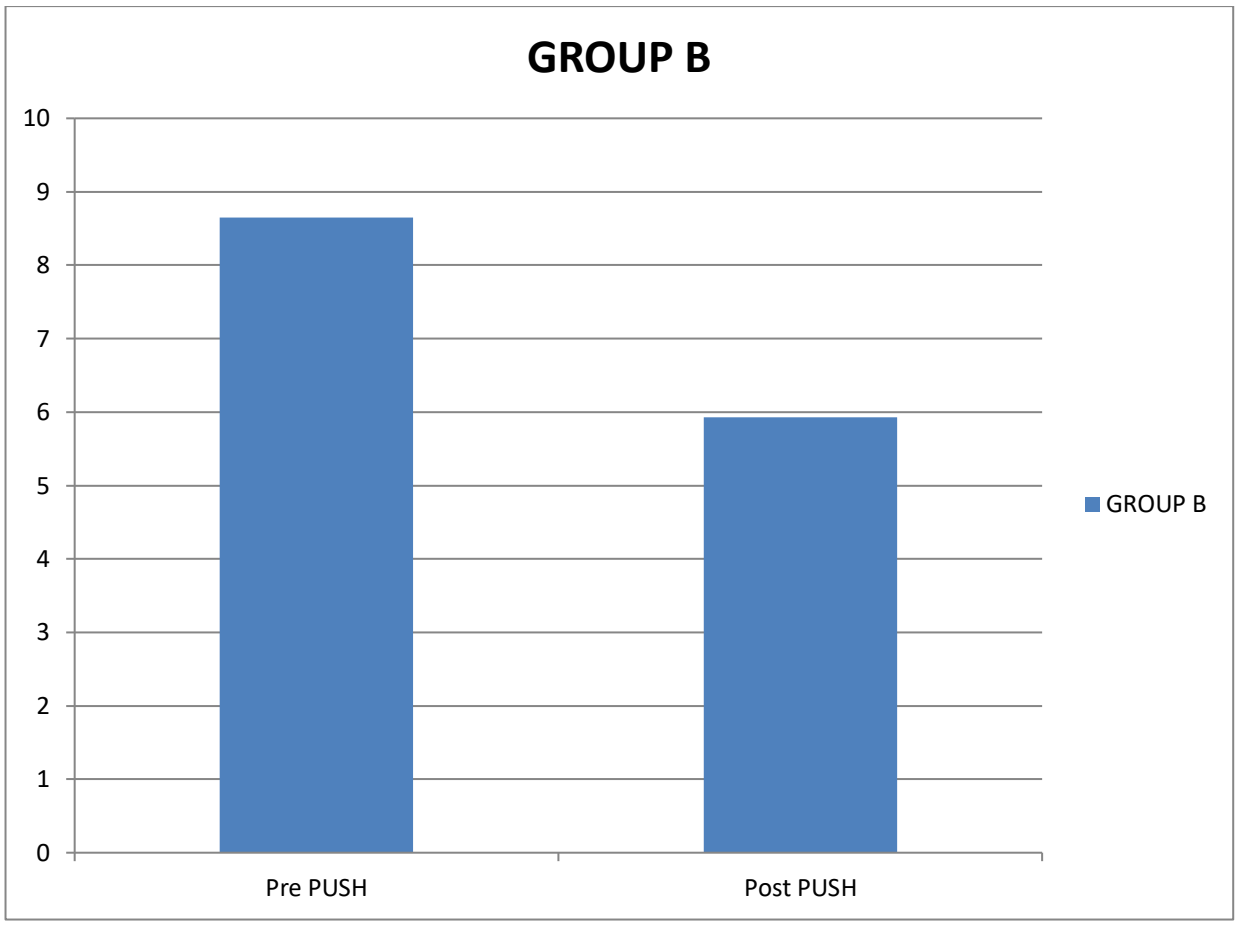
In this study , comparsion of healing of diabetic plantar foot ulcers treated with conventional measures alone with healing of diabetic plantar foot ulcers treated with conventional measures along with bohler iron plaster cast has been made.

Patients included in this study are categorized into group A and group B.Patients in the group A and group B are evaluvated with help of pressure ulcer scale for healing(PUSH) score before and after intervention. Each group constitutes 30 patients and their PUSH scores are calculated individually and compared between the two groups.

COMPARISON OF PRE PUSH AND POST PUSH SCORES



In the group A , means of pre PUSH score is 10.27 and means of post PUSH score is 7.60 .There is decrease post PUSH score after intervention which has been statistically measured.



In the group B , means of pre PUSH score is 8.65 and means of post PUSH score is 5.93 .There is a decrease in post PUSH score after intervention which has been statistically measured.

The test is statistically significant with the p value <0.05 , thus confirming that there is significant decrease in size, exudate and tissue type ,thus augmenting healing process in diabetic ulcer foot patients.

CONCLUSION

The study revealed that healing of diabetic foot ulcers treated with conventional measures along with bohler ion plaster cast facilitates better healing when compared with that of ulcers treated with conventional measures alone.

This has been evident by calculating pressure ulcer scale for healing (PUSH) scores before and after intervention .

On analysis ,it is found that there is significant decrease in ulcer size ,exudate amount and change in type of tissue when treated with conventional measures along with bohler iron plaster cast.

Thus by using appropriate offloading device which enables pressure dispersion from the ulcer site promotes better wound healing of diabetic plantar foot ulcers thereby preventing major complications which results in morbidity and mortality in most diabetic patients.

SUMMARY

- This is a prospective study of 60 patients of diabetic plantar foot ulcers in Madurai Medical College.
- The most common complication of diabetes is diabetic ulcer foot disease ,which left untreated can lead to unexpected consequences like amputation.
- The major tenets in diabetic ulcer foot healing are debridement, dressings and offloading.
- Offloading devices enable dispersion of pressure from the ulcer site
- Diabetic plantar foot ulcers treated with conventional measures along with bohler iron plaster cast facilitates better wound healing when compared with those treated with conventional measures alone which has been evident by PUSH scores.

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INFORMED CONSENT

Name: Age/sex: IP:

I herewith declare that I have been explained in a language fully understood by me regarding the purpose of this study, methodology, proposed intervention, plausible side effects, if any and sequelae.

I have been given an opportunity to discuss my doubts and I have received the appropriate explanation.

I understand that my participation in this study is completely voluntary and that I am free to withdraw from this study at anytime without any prior notice or without having my medical or legal rights affected.

I permit the author and the research team full access to all my records at any point, even if I have withdrawn from the study. However my identity will not be revealed to any third party or publication.

I hereby permit the author and the research team to use my results and conclusion arising from this study for any academic purpose, including but not limited to dissertation/thesis or publication or presentation in any level.

Therefore , in my conscience, I give consent to be included in the study and to undergo any investigation or any intervention herein.

Patient ‘s sign Investigator’s sign

PROFORMA

Name :

Age :

Sex: Height: Weight:

Duration of Diabetes:

General Physical Examination:

Body build and nourishment

Hydration

Anaemia/jaundice/cyanosis/clubbing/generalized

lymphadenopathy

Pedel edema/skin changes /foot deformities

Pulse/Blood pressure/Temperature

Other Systemic Examination

Peripheral arterial pulsations

Local examination of ulcers:

1. Number of ulcers
2. Size
3. Amount of exudates
4. Tissue type

Investigations

Blood sugar

Blood urea

Blood creatinine

Urine routine

Complete blood haemogram

HIV/HBsAg

Swab C/S

Doppler study of lowerlimbs

MASTER CHART

GROUP A

S.NO	NAME	AGE	SEX	OP NO	PRE PUSH SCORE		POSTPUSH SCORE	
					a+b+c	total	a+b+c	total
1	Petchiammal	45	F	201652	5+2+2	9	4+1+2	7
2	Saraswathi	30	F	212658	4+1+3	8	3+1+2	6
3	Pitchaimani	54	M	256743	6+2+3	11	5+1+2	8
4	Govindharaj	72	M	197662	8+2+3	13	6+2+2	10
5	Salaikumaran	57	M	243768	6+2+3	11	5+2+3	10
6	Karupayee	45	F	179443	5+2+2	9	4+1+2	7
7	Solaiammal	36	F	185634	7+3+3	13	5+2+2	9
8	Rasathi	48	F	297435	5+2+3	10	3+2+2	7
9	Perumal	69	M	258536	9+2+3	14	7+2+2	11
10	Mohammed Ibrahim	43	M	326362	5+1+2	8	4+1+2	7
11	Vijayalakshmi	38	F	183429	4+1+3	8	3+1+2	6
12	Joseph	50	M	154289	4+2+3	9	3+2+2	7
13	Alagarsamy	49	M	163428	8+2+3	13	6+2+2	10
14	Muniyandi	66	M	267543	7+3+4	14	6+2+2	10
15	Puvathaal	77	F	127430	5+2+2	9	3+2+2	7

S.NO	NAME	AGE	SEX	OP.NO	PRE PUSH SCORE		POSTPUSH SCORE	
					a+b+c	total	a+b+c	total
16	Selvi	30	F	243823	5+1+1	7	3+1+0	4
17	Raja	37	M	342976	6+2+3	11	3+1+2	6
18	Fazil Ahmed	42	M	285321	6+1+2	9	5+1+2	8
19	Asha	39	F	153674	6+1+2	9	4+1+2	7
20	Karupan	50	M	214825	5+2+3	10	3+1+3	7
21	Sasikala	33	F	316984	5+1+3	9	3+1+2	6
22	Christopher	39	M	215438	5+1+2	8	4+1+2	7
23	Mariyappan	53	M	174328	6+2+3	11	5+1+2	8
24	Naveen	39	M	256732	4+1+3	8	3+1+2	6
25	Rakayee	56	F	324512	6+2+2	10	4+1+2	7
26	Dayanithi	44	M	241365	6+2+2	11	4+1+2	7
27	Manunithi	36	M	276733	4+1+2	7	2+1+0	3
28	Mokappan	59	M	196843	9+2+3	14	7+2+2	11
29	Murali	49	M	193672	5+2+2	9	4+1+2	7
30	Natchiammal	80	F	187689	9+3+4	16	7+2+3	12

GROUP B

S.NO	NAME	AGE	SEX	OP.NO	PRE PUSH SCORE		POST PUSH SCORE	
					a+b+c	total	a+b+c	total
1	Kuruvammal	69	F	247542	5+2+3	10	4+1+2	7
2	Manikandan	42	M	175342	3+2+2	7	3+1+1	5
3	Sethupathy	37	M	143897	3+1+3	7	2+0+2	4
4	Arumugam	51	M	194523	3+2+3	8	2+1+2	5
5	Chinnathevar	74	M	221894	5+3+4	12	5+1+2	8
6	Senniyammal	39	F	216534	4+1+2	7	4+0+2	6
7	Virumandi	48	M	172154	4+2+2	8	3+1+1	5
8	Veeraiyan	58	M	267321	5+2+3	10	4+1+2	7
9	Salman	33	F	283452	2+1+1	4	1+0+1	2
10	Kuppan	43	M	132121	5+2+2	8	4+1+2	7
11	Angelin	35	F	225432	4+1+2	7	4+0+2	6
12	Meenakshisundaram	55	M	251423	6+2+2	10	5+1+2	8
13	Manickam	43	M	283224	4+2+2	8	2+1+2	5
14	Rasathiammal	59	F	275432	4+2+2	8	3+1+2	6
15	Soundarapandiyan	37	M	245327	4+2+2	8	2+0+2	4

S.NO	NAME	AGE	SEX	OP.NO	PRE PUSH SCORE		POST PUSH SCORE	
					a+b+c	total	a+b+c	total
16	Pechithevar	60	M	315632	8+2+3	13	6+1+2	9
17	John samuvel	39	M	286431	4+2+2	8	3+0+1	4
18	Mary	51	F	231089	7+2+3	12	5+2+2	9
19	Srinivasan	57	M	195634	4+2+1	7	3+1+1	5
20	Mullai Pandiyan	49	M	280945	4+2+2	8	2+1+2	5
21	Sollamalai	53	M	200167	6+2+2	10	5+1+2	8
22	Nallammal	36	F	289345	3+2+3	8	2+0+2	4
23	Senthilkumaran	40	M	320019	4+2+2	8	3+0+1	4
24	Sekar	58	M	197251	4+2+2	8	3+1+2	6
25	Ahmed	45	M	139023	4+2+2	9	3+1+1	5
26	Paapammal	49	F	327572	3+2+3	8	2+0+2	4
27	Elangovan	51	M	231412	7+2+3	12	5+2+2	9
28	Vijayan	47	M	198654	4+2+2	8	4+1+2	7
29	Saravanan	40	M	218903	4+1+2	7	4+0+2	6
30	Sivaraj	32	M	222450	6+3+3	12	5+1+2	8

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MADURAI, TAMILNADU, INDIA -625 020
(Affiliated to The Tamilnadu Dr.MGR Medical University,
Chennai, Tamil Nadu)

Prof Dr V Nagaraajan MD MNAMS
DM (Neuro) DSc.,(Neurosciences)
DSc (Hons)
Professor Emeritus in Neurosciences,
Tamil Nadu Govt Dr MGR Medical
University
Chairman, IEC

Dr.M.Shanthi, MD.,
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Madurai Medical College, Madurai.

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Advocate, Palam Station Road,
Sellur.

8.Thiru.P.K.M.Chelliah, B.A.,
Businessman,21, Jawahar Street,
Gandhi Nagar, Madurai.

ETHICS COMMITTEE CERTIFICATE

Name of the Candidate	:	Dr.D.Premkumar
Course	:	PG in MS., General Surgery
Period of Study	:	2016-2019
College	:	MADURAI MEDICAL COLLEGE
Research Topic	:	Comparative study on healing of diabetic plantar foot ulcers treated by conventional measures alone vs conventional measures along with bohler iron plaster cast
Ethical Committee as on	:	23.01.2018

The Ethics Committee, Madurai Medical College has decided to inform that your Research proposal is accepted.

Member Secretary Chairman Dean / Convenor

16 APR 2018

DEAN
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Instances where selected sources appear:

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CERTIFICATE II

This is to certify that this dissertation work titled , “COMPARATIVE STUDY ON HEALING OF DIABETIC PLANTAR FOOT ULCERS TREATED BY CONVENTIONAL MEASURES ALONE VS CONVENTIONAL MEASURES ALONG WITH BOHLER IRON PLASTER CAST” of the candidate Dr.D.Premkumar with registration number 221611118 for the award of MASTER DEGREE in the branch of GENERAL SURGERY.

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